SALIVA-BASED FERTILITY TEST

Geratherm®
ovu control

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INSTRUCTION MANUAL

Geratherm® ovu control
GT-OVU04

CE 0118

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Please read these instructions carefully.

The Geratherm® ovu control is a diagnostic medical device for determining a woman's periods of fertility and infertility. It is explicitly stated that this product is **not** a contraceptive device.

The reliability of the procedure depends on the user following the instructions correctly and evaluating the results correctly.
It is urgently recommended that you consult a physician when you begin family planning.

DESCRIPTION OF THE DEVICE

The Geratherm® ovu control consists of four components: the casing, the lighting system, the optical system (lens) and the lid.

TECHNICAL DATA

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Magnification:	50-fold	
Dioptre:	+/- 5	
Batteries:	2 x LR44 1.5 V	
Light source:	LED diodes	
Dimensions:	67 x 22 x 22 mm	
Weight:	39 g	
Operating and storage between uses conditions:	Temperature:	+15 °C to +30 °C
	Air humidity:	10 - 70 %
	Atmospheric pressure:	50 - 106 kpa
Transport and storage conditions:	Temperature:	0 °C to +70 °C
	Air humidity:	10 – 95 %
	Atmospheric pressure:	50 - 106 kpa
IP code (protection rating):	IP22 (effective against bigger solid bodies; protected against dripping water)	

Quality guarantee:
Geratherm® is certified in accordance with Council Directive 93/42/EEC, Annex II and DIN EN ISO 13485 and is entitled to affix the CE-mark CE 0118 (LMET Notified Body).

TECHNICAL DATA

Note:
If the device is used outside of the specifications, proper function is no longer guaranteed!
We reserve the right to make technical changes to improve and further develop the product.
This device and its accessories comply with European standards EN60601-1 et seq. and is subject to special safety measures in terms of electromagnetic tolerance.

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Electromagnetic compatibility:
The device complies with current specifications with regard to electromagnetic compatibility and is suitable for use in all premises, including those designated for private residential purposes. The radio frequency emissions of the device are extremely low and in all probability do not cause any interference with other devices in the proximity.

GENERAL INFORMATION

A woman's regular and stable menstrual cycle is 28 days in duration. About 14 days after the start of the last period and 15 days before the start of the next period, the rising level of oestrogen in the blood leads to ovulation.
The biological characteristics of the egg cell mean that fertilisation is only possible within about 24 hours after ovulation.
Since the male sperm cells can survive for up to 72 hours, conception is usually possible during the 'fertile window' between about 2 days before and 1 day after ovulation.

IMPORTANT NOTES

1. Certain medications or hormone treatments, as well as smoking, acute inflammations in the mouth or throat, and alcohol can temporarily alter the composition of saliva and thereby affect the result.

2. Before applying the saliva, check that the outer, smooth surface of the lens is clean.

3. For reasons of hygiene and health, it is recommended that the device be used by one individual only.

4. Do not expose your device to intense heat or cold.

5. Never immerse the device in water or other fluids.

6. Do not clean it under running water.

7. Do not drop the ovu control device and do not subject it to sudden impacts.

8. Protect it from dust, dampness and heat.

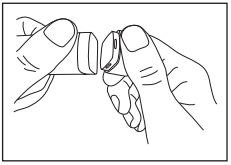
9. Do not modify or disassemble the device.

10. Keep out of the reach of unsupervised children. Consumables could be swallowed.

11. Damaged devices should not be used.

CHANGING THE BATTERIES

First remove the blue casing. You can change the batteries by pushing the white cover off by tipping it to the side.



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Replace the empty batteries (2 x LR44 1.5 V) with new ones. Pay attention to correct polarity; the positive pole of both batteries must be in the correct position. Push the white cover back onto the device.

USE

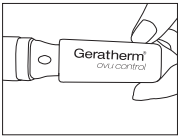
Note:

1. Use the Geratherm® ovu control **before** eating, drinking, cleaning your teeth or smoking, or at least **3 hours after** eating, drinking, cleaning your teeth or smoking.

2. In the early morning hours the saliva can be thick. This can falsify the test result. In this case, carry out the test later in the morning or in the afternoon, when the saliva is more watery.

3. Clean the lens with a dry cloth **before and after each** use.

USE



Step 1

Remove the long blue protective cap from the Geratherm® ovu control.

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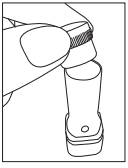

Step 2

Carefully remove the lens by pulling it off the casing. Carefully clean the outer (smooth) surface of the glass with a dry dust-free cloth.

Step 3

Preferably in the morning, before eating breakfast, cleaning your teeth or smoking, place a drop of saliva on the middle of the lens using a clean and dry finger. Dab the saliva onto the lens from above, without smearing the drop.
Ensure that no air bubbles or foam are on the lens. Leave the saliva sample to dry at room temperature for about 10 to 15 minutes. To do this, lay the lens aside with the drop uppermost.

Note:
You can stimulate the production of saliva by biting gently on your tongue.

USE

Step 4

Place the lens with the completely dried drop of saliva inside the casing of the device.

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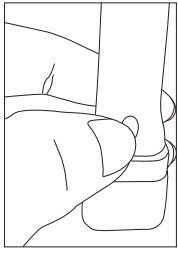

Step 5

Push the button to activate the light switch. If necessary, remove any visual aids. While pressing the light switch, look through the upper section of the device with the inserted lens so as to view your test result. You do not need to adjust the focus, because the device has an autofocus optical system. Look closely and carefully at the sample in order to evaluate your result correctly.

Note:
Should no structure at all be visible when you examine the sample, remove the optical system from the casing and wait a few more minutes until the sample is completely dry before repeating the test.

Step 6

Clean the lens after each use, either with the spectacle cleaning cloth provided or with a clean dry cloth. Do not immerse the ovu control in water. Replace the blue cap on the casing after use.

INTERPRETATION OF RESULTS

It is scientifically proven that there is a direct correlation between the increase in oestrogen levels and the time of ovulation. Oestrogen can be detected in saliva, as well as elsewhere in the body. During a woman's fertile days, the salt content in the saliva rises owing to the increased oestrogen production. The salt crystals that form in dried saliva have a fern-like structure. This 'ferning pattern' can be seen most clearly directly before ovulation.
During the infertile days this 'ferning pattern' disappears owing to the increasing level of progesterone, and a gravel-like pattern is seen instead.

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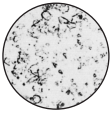

INFERTILE
Conception is unlikely

You see a gravel-like pattern with dots and bubbles. You are most probably not fertile.

TRANSITION PHASE – LESS FERTILE
Conception is possible, but unlikely

A few crystals with a slight 'ferning pattern' are visible. You are 3 - 4 days before ovulation. This is the start of the fertile period.

FERTILE
Conception is highly probable

The 'ferning pattern' is clearly visible. Ovulation has begun. Fertility lasts about 3 days. During these fertile days sexual intercourse is recommended if you wish to conceive.

INTERPRETATION OF RESULTS

Changes to the 'fern pattern' can be caused by the following:

- After discontinuing the use of hormonal contraceptive agents (e.g. 'the pill')
- During use of contraceptive coils (IUDs)
- After a birth, during and after lactation
- Medical conditions or products which alter the composition of mucus secretions (e.g. expectorant medications)

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EVALUATION CALENDAR (Example for the month of January)

The values recorded in an evaluation calendar are important for determining the fertile phase.
Carefully filled in record sheets provide important diagnostic information and you should always take them with you when you visit your doctor.
Start recording on the first day of a menstrual period. New evaluation calendars can be downloaded from the Geratherm® homepage by clicking on the following link:
http://www.geratherm.com/en/health-care-3/download-area/

EVALUATION CALENDAR
(Example for the month of January)

Geratherm® ovu control

My fertility calender

Month/day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
January	☺	☺	☺	☺	☺	☺	☺	☺	☹	☺	☺	☺	☺	☺	☺	☺	☹	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺
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April																															
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June																															
July																															
August																															
September																															
October																															
November																															
December																															

☺ Fertile ☺ Less fertile ☹ Infertile ■ Period ◪ Intermenstrual bleeding

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CLEANING

Clean the lens (glass slide) with a dry, fuzz-free cloth. Do not clean it under running water.
Do not use soap or detergent for cleaning the lens. Residues may interfere with the crystallisation process!

DISPOSAL

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Observe the applicable regulations when disposing of the device and batteries.
This product must not be disposed of together with domestic waste.
Please remove the batteries before disposing of the device/unit.
Do not dispose of old batteries with your household waste, but at a battery collection station at a recycling site or in a shop.

WARRANTY

The Geratherm® ovu control is guaranteed against manufacturer's defect for one year from the date of purchase. This guarantee does not cover any damage to your product that is caused by improper handling.

The manufacturer is not responsible and cannot be held liable for improper use or the false interpretation of the result.

Please read
the user manual!

Manufacturer:
Geratherm Medical AG
Fahrenheitstraße 1
D-98716 Geschwenda
Germany

CE 0118

CERTIFICATE OF GUARANTEE

Geratherm® guarantees the ovu control against any manufacturing defect for one year from the date of purchase if it is returned to the dealer from whom it was purchased. During this period the unit will be repaired or replaced free of charge if the fault is due to defective design or assembly.
This guarantee does not cover any damage or defect caused by improper handling resulting from use that is not in compliance with these instructions, or caused by unauthorised attempts to repair it. Your local dealer cannot declare this manufacturer's guarantee invalid, but may expand it by additional guarantees at his discretion and at his own expense.

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Model No.: .....

Serial No.: .....

Date of purchase: .....

Dealer's signature: .....

Invoice No. / Receipt No.: .....

Manufacturer:

Geratherm Medical AG
Fahrenheitstraße 1
D-98716 Geschwenda
Germany

FERTILITY TEST
Geratherm® ovu control
GT-OVU04